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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,763	11/26/2003	Eiji Mori	081356-0207	6356

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EXAMINER	
MACIAS, CHANDA L	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,763	MORI ET AL.	
	Examiner	Art Unit	
	Chanda L. Macias	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-108* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed June 7, 2004 is acknowledged and has been entered.

2. Claims 1-108 are pending in the application and are currently subject to restriction.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-104, and 108, insofar as the claims are drawn to an antibody or a functional fragment thereof, binding to a TRAIL receptor, classified, for example, in class 530, subclass 387.1.

Group II. Claims 105-107, insofar as the claims are drawn to a method for preventing or treating tumors, comprising administering the antibody or the functional fragment thereof, classified, for example, in class 424, subclass 130.1.

4. The inventions are distinct, each from the other because of the following reasons:

The inventions of Group I are products, whereas the inventions of Groups II are processes.

The inventions of Group I and the inventions of Groups II are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

instant case, the product as claimed, namely the antibody can be used in a materially different process of using that product, such as the process of using affinity chromatography.

The inventions of Groups I and II have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter, and the search performed in examining claims drawn to a product is a different from the search performed in examining claims drawn to a process using that product. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims of Group I would not suffice to provide adequate information regarding the merit of the claims of Group II, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Groups I and II, an examination of both would constitute a serious burden.

Since the inventions of Groups I and II have been shown to be patentably distinct, and because the examination of both inventions could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

5. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

6. This application contains claims 1-108 directed to patentably distinct species of the inventions of Groups I or II, wherein said antibody is selected from the group

consisting of (a) antibody which binds to TRAIL-R1, (b) antibody which binds to TRAIL-R2, and (c) antibody which binds to both TRAIL-R1 and TRAIL-R2.

Each species of invention is patentably distinct from the others since each involves making and/or using an antibody having different binding specificity. The antibody either binds TRAIL-R1 without binding TRAIL-R2, or binds TRAIL-R2 without binding TRAIL-R1 or binds both TRAIL-R1 and TRAIL-R-2. Moreover, the antibody necessarily recognizes and binds to a unique antigenic determinant of TRAIL-R1, which is not shared by TRAIL-R2, or it recognizes and binds to a unique antigenic determinant of TRAIL-R2, which is not shared by TRAIL-R1, or it recognizes and binds to an antigenic determinant shared by both TRAIL-R1 and TRAIL-R2. Accordingly, the examination of claims directed to any one species of invention would require a unique search that is not required for examination of any of the other species of invention, because the search of any one member of the genus of antibody will not provide adequate information regarding any other. Moreover, the search necessary to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search necessary to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to restrict these species of invention and require Applicant to elect only one. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the one antibody to which the claims of elected group of inventions will be directed during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that novelty and nonobviousness of the elected species of invention would render claims directed to that species allowable over the prior art, but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. This application contains claims 105-107 directed to patentably distinct species of the invention of Group II, wherein said "tumor" is selected from the group consisting of (a) colon cancer, (b) colorectal cancer, (c) lung cancer, (d) breast cancer, (e) brain tumor, (f) malignant melanoma, (g) renal cell carcinoma, (h) bladder cancer, (i) leukemia, (j) lymphomas, (k) T cell lymphomas, (l) multiple myeloma, (m) gastric cancer, (n) pancreas cancer, (o) cervical cancer, (p) endometrial carcinoma, (q) ovarian cancer, (r) esophageal cancer, (s) liver cancer, (t) head and neck squamous cell carcinoma, (u) cutaneous cancer, (v) urinary tract carinoma, (w) prostate cancer, (x) choriocarcinoma, (y) pharyngeal cancer, (z) laryngeal cancer, (aa) thecomatosis, (bb) androblastoma, (cc) endometrium hyperplasy, (dd) endometriosis, (ee) embryoma, (ff) fibrosarcoma, (gg) Kaposi's sarcoma, (hh) hemangioma, (ii) cavernous hemangioma, (jj) angioblastoma, (kk) retinoblastoma, (ll) astrocytoma, (mm) neurofibroma, (nn) oligodendroglioma, (oo) medulloblastoma, (pp) ganglioneuroblastoma, (qq) glioma, (rr) rhabdomyosarcoma, (ss) hamartoblastoma, (tt) osteogenic sarcoma, (uu) leiomyosarcoma, (vv) thyroid sarcoma, and (ww) Wilms tumor.

Each species of invention is patentably distinct from the others for the following reasons:

Each type of "tumor" is etiologically and pathologically distinct from the others, since, for example, each originates from a different type of tissue or cell, or manifests clinically distinct symptoms. Some of the different types of "tumors" are cancerous (i.e., malignant); others are not cancerous (e.g., endometriosis). Additionally, among many other differences; each type of "tumor" is associated with different risk factors; each type of "tumor" is associated with a different set of diagnostically useful molecular markers; each type of "tumor" differentially expresses proteins that are therapeutically useful in

targeting therapeutic agents to the "tumor"; each type of "tumor" is more or less responsive to particular therapeutic agents; and each type of cancerous "tumor" is more or less likely to metastasize. Accordingly, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the examination of claims directed to any one type of cancer requires a unique search that is not required for examination of claims directed to any other type of cancer and will not provide adequate information regarding any other. Moreover, the search required to examine claims directed to any one species of invention is not the same, nor is it coextensive with the search required to examine claims directed to any other. Since having to perform more than one search would constitute a serious burden, it is proper to require Applicant to elect a single species of invention. See MPEP § 809.

Applicant is required under 35 U.S.C. 121 to specifically elect a single species of invention by identifying the type of "tumor" to which the claims of the elected invention will be drawn during prosecution on the merits, and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that to the extent that claims are drawn to a novel and nonobvious species of invention, the claims are allowable over the prior art but not necessarily over the requirements set forth under 35 U.S.C. §§ 101 and 112.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species, which are written in dependent form, or otherwise, include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chanda L. Macias, Ph.D. whose telephone number is (571) 272-9032. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chanda L. Macias, Ph.D.
Examiner
Art Unit 1643

clm
April 30, 2006

/STEPHEN RAWLINGS/
PRIMARY EXAMINER
ART UNIT 1643